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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.           | CONFIRMATION NO. |
|--|-------------|----------------------|-------------------------------|------------------|
| 09/067,638   | 04/28/1998  | LEX M. COWSERT       | ISIS-2960                     | 1414             |
| 7590 10/12/2006<br>PAUL K. LEGAARD, Ph.D.<br>COZEN O' CONNOR<br>1900 MARKET STREET<br>PHILADELPHIA, PA 19103 |             |                      | EXAMINER<br>MORAN, MARJORIE A |                  |
|  |             |                      | ART UNIT<br>1631              | PAPER NUMBER     |

DATE MAILED: 10/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                                      |                                       |  |
|------------------------------|--------------------------------------|---------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>09/067,638 | <b>Applicant(s)</b><br>COWSERT ET AL. |  |
|                              | <b>Examiner</b><br>Marjorie A. Moran | <b>Art Unit</b><br>1631               |  |

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12 July 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 83-87 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 83-87 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/26/06 has been entered.

Claims 83-87 are pending. All rejections and objections not reiterated below are hereby withdrawn.

The terminal disclaimer filed on 5/26/06 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of 09/295,463 has been reviewed and is accepted. The terminal disclaimer has been recorded.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 87 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which

was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a NEW MATTER rejection.

A step of searching a database for alternative transcripts for a selected nucleic acid, as recited in amended claim 87, is new matter. In the response filed with the amendment of 5/26/06, applicant does not point to support in the originally filed disclosure for the new limitation. The original claims did not recite any limitations regarding searching databases nor alternative transcripts. Original Figure 3 discloses a step "212" of searching for additional target information, but does not disclose that the "additional" information is alternative transcripts. The original specification, on page 15, discloses that multiple transcripts such as those resulting from alternative splicing, may be unique targets for use in the inventive method, but does not disclose that the multiple transcripts are those found in a database nor does the original specification disclose searching at least one database for any kind of transcript, specifically "alternative" ones. As the newly recited limitation is not supported by the original disclosure, claim 87 recites new matter, and is rejected.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 83-87 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 83, 85, 86, and 87 each recites a step (iii) reciting generating a subset of virtual oligonucleotides “based on” targeting a functional region....” It is unclear what limitation of the subset is intended nor what relationship is intended between the set of virtual oligonucleotides and the functional region, etc. by the limitation that one be “based on” another. For example, are the oligonucleotides in the generated set those which hybridize to a target region? Or those which interact with another molecule which binds to the target region? Or are they those which do NOT “interact” with a target region? As the limitation and relationship intended by use of the phrase “based on” are unclear, the claims are indefinite.

Claims 83, 85, 86, and 87 recite the term “targeting” in a step (iii). It is unclear what is meant by “targeting,” i.e. binding, inhibiting, cleaving, activating, hybridizing, or some other meaning, therefore the claims are indefinite. Further, it is unclear what is intended to “target” the functional region; i.e. the entire set, just the generated subset, or just individual oligonucleotides which happen to be part of the generated set, therefore the claims are further indefinite.

Claims 85, 86 and 87 recite the phrase “target accessibility,” each in step (iii). It is unclear what the “target” is intended to be, and what the target is intended to be “accessible” to. Part (a) of each claim indicates that a “target” is a functional region of the selected nucleic acid recited in the preamble of each claim. However, part (b) of

each claim specifically recites “target accessibility TO said selected nucleic acid,” thereby indicating that the “target” is intended to be something OTHER than the selected nucleic acid. As the combination of steps (a) and (b) renders it unclear just what a “target” is intended to be, the claims are indefinite.

Each of claims 85-87 recites a limitation (c) in step (iii) of a “uniform distribution of oligonucleotide compounds across said selected nucleic acid.” It is unclear what this phrase is intended to represent; i.e. fragments of the selected nucleic acid itself, wherein the fragments are generated such that they represent a “uniform distribution” taken from the parent sequence, complementary sequences which hybridize “uniformly” (completely?) to the selected nucleic acid, other sequences which bind to the nucleic acid “uniformly” across its length, etc. As it is unclear what limitation is intended by this phrase, the claims are indefinite.

Each of claims 83 and 85-87 recite the phrases “said set of real oligonucleotides” and “said real oligonucleotides” in a paragraph beginning “an apparatus.” There is no antecedent basis for either phrase as none of the claims recites “a set of real oligonucleotides” nor “real oligonucleotides” anywhere, thus the claims are indefinite.

Claim 85 recites a second apparatus which is limited to be “liquid chromatography,” “mass spectroscopy,” gel fluorescence,” scintillation imaging,” or capillary gel electrophoresis.” All of these are techniques or methods of performing measurements using an apparatus; none actually IS an apparatus. It is unclear what apparatus are actually intended; for example, capillary gel electrophoresis may be performed any number of ways using a great variety of different platforms/supports,

gels, electrophoretic means, etc., therefore recitation of the method cannot be interpreted to be directed to or “imply” any single apparatus. As the limitations intended are unclear, claim 85 is indefinite.

Claim 85 recites a “second apparatus” in its final paragraph, but fails to recite any relationship between the second apparatus and any other limitation in the claim. It is unclear what functional or physical relationship, if any, is intended between the second apparatus and any other elements of the claimed system, therefore the claim is indefinite.

Claim 86 recites a procedure which identifies members of a set which modulate expression of a selected nucleic acid, and in the last line, limits a property to “modulating said selected nucleic acid.” The limitation of the last line appears to be redundant, and is thus confusing. As it is unclear what limitation is actually intended, the claim is indefinite.

Claim 86 recites the term “said property” in the last line. There is no antecedent basis for this term in the claims, therefore claim 86 is indefinite.

Claim 84 depends from claim 83 and is indefinite for the same reasons as those set forth above for claim 83.

### ***Conclusion***

Claims 83-87 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie A. Moran whose telephone number is (571)

272-0720. The examiner can normally be reached on Monday-Friday; 6 am-2:30 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571)272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Marjorie A. Moran  
Primary Examiner  
Art Unit 1631

*Marjorie A. Moran*  
10/11/06